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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,531	03/15/2004	Samuel Achilefu	1448.2:H US (073979.40)	2309
27805	7590	06/10/2009		
THOMPSON HINE L.L.P. Intellectual Property Group P.O. BOX 8801 DAYTON, OH 45401-8801			EXAMINER JONES, DAMERON LEVEST	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 06/10/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/800,531		ACHILEFU ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	D L. Jones		1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 32-35 and 45-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-35 and 45-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 2/26/09 wherein claims 1-31 and 36-44 are canceled; claim 32 was amended; and claim 51 was added.

**Note:** Claims 32-35 and 45-51 are pending.

## **RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS**

2. The Applicant's arguments and/or amendment filed 2/26/09 to the rejection of the claims made by the Examiner under 35 USC 103 and/or 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

### **112 First Paragraph Rejection (Scope of Enablement)**

The rejection of claims 32-35, 45-50, and newly added claim 51 under 35 USC 112, first paragraph, because the specification while being enable for some cyanine dyes, does not reasonably provide enablement for all cyanine or indocyanine dyes is MAINTAINED for reasons of record in the office action mailed 1/7/09 and those set forth below.

In summary, Applicant discloses the dictionary definition (i.e., as defined by Hawley's Chemical Dictionary) of cyanine and asserts that while the specification disclose specific cyanine and indocyanine dyes, a person of ordinary skill in the art appreciates that Formulae 2 and 4 in the specification are directed to indocyanine dyes. Hence, Applicant concludes that the rejection has been overcome by the amending of the claim.

Applicant's arguments are non-persuasive for reasons of record in the office action mailed 1/7/09 and those below. According to the Wikipedia encyclopedia

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(Cyanine - Retrieved from Wikipedia (<http://en.wikipedia.org/wiki/Cyanine>), June 2009, four pages, see attachment), for example, the term 'cyanine' is a non-systematic name of a synthetic dye family belonging to the polymethine group. There are three types of cyanines (a) open chain cyanine,  $R_2N^+=CH[CH=CH]_n-NR_2$ ; (b) hemicyanines (structures contain one aryl group on one end of the structure),  $Aryl=N^+=CH[CH=CH]_n-NR_2$ ; and closed chain cyanines (structures contain two aryl groups, one on each end of the structure),  $Aryl=N^+=CH[CH=CH]_n-N=Aryl$ . As a result, the term 'cyanine', for example, encompasses structural distinct groups of compounds. Furthermore, the cyanines formula set forth in Applicant's disclosure involve closed chain cyanines which are not structurally the same as open chain and hemicyanines. As a result, Applicant is not entitled to all cyanines and indocyanines. Also, it is noted that in the background of the instant invention, Applicant discloses attempts have been made to incorporate various heteroatoms and cyclic moieties into the chain of cyanine and indocyanine dye systems which results in various differences between the dyes (see PG Pub 2004/0241095, page 1, paragraphs [0005] - [0008]). Hence, Applicant concluded that there is a need for dyes that do not aggregate in solution and addressed the 'problem' using *cyanine and indocyanine dyes with specific general formulae (the dyes involve closed chain cyanines)* in combination with a biocompatible organic solvent. Therefore, the scope of enablement rejection is deemed proper.

### **112 Second Paragraph Rejections**

The rejection of claims 32-35, 45-50, and newly added claim 51 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and

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distinctly claim the subject matter which Applicant regards as the invention is  
MAINTAINED for reasons of record in the office action mailed 1/7/09 and those set forth  
below.

In summary, Applicant makes the same assertions as set forth in the 112, first  
paragraph, rejection section above.

Applicant's arguments are non-persuasive, because based on what is known in  
the art about how cyanine and indocyanine dyes vary structurally, one of ordinary skill in  
the art would not be able to predict, without some undue experimentation, which  
cyanine and indocyanine species are compatible with the instant invention. Hence, the  
rejection is deemed proper because the terms are vague and indefinite as it relates to  
which species are encompassed by the instant invention.

### **103 Rejection**

The text of those sections of Title 35, U.S. Code not included in this action can  
be found in a prior Office action.

The rejection of claims 32-35 under 35 USC 103(a) as being unpatentable over  
Licha et al (US Patent No. 6,083,485) is MAINTAINED for reasons of record in the office  
action mailed 1/7/09 and those set forth below.

Applicant's asserts that the rejection should be withdrawn because while Licha et  
al renders obvious a composition comprising a cyanine dye and cyclodextrin, the  
cyclodextrin is added for a purpose different from that of the instant invention.  
Specifically, Applicant asserts that cyclodextrin is added to the invention of Licha et al to  
improve stability, not enhance fluorescence.

Applicant's argument is non-persuasive because a skilled artisan would recognize that if Applicant and the prior art disclose the same composition, then the compositions would inherently behave the same. As a result, the prior art's composition, like Applicant's would enhance fluorescence. Furthermore, since the prior art specifically discloses that cyclodextrin is a preferred compound to be added to the dye, the skilled artisan would be motivated to incorporate it into the dye mixture. Thus, the rejection is deemed proper.

**Note:** In regards to Applicant's question as to whether or not claims 32-34 are rejected under Licha et al since only claim 35 discloses that the solvent is cyclodextrin, it should be noted that claim 35 depends on independent claim 32. Thus, since claim 32 only requires that a dye (i.e., cyanine) in combination with a biocompatible solvent be present, then, 'yes' the prior art reads on independent claim 32. Likewise, since claims 33 and 34 are limited to a particular solvent, then 'yes', those claims read on the solvent being cyclodextrin and are rejected under Licha et al. Hence, claims 32-35 are rejected under Licha et al which render obvious a dye composition comprising a cyanine dye and cyclodextrin.

#### **COMMENTS/NOTES**

3. It is duly noted that prior art has not been cited over all of Applicant's claims. Specifically, all of the organic solvents. Thus, as stated previously, the specific solvents in combination with the specific cyanine and indocyanine dyes is not render obvious by the prior art. Hence, Applicant may want to consider amending independent claim 32 to

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include the specific solvents of newly added claim 51 in combination with the cyanine/indocyanine dyes Applicant is enabled for.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D L. Jones/  
Primary Examiner  
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June 4, 2009